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August 29, 2008

Acting Administrator Kerry N. Weems
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1403-P
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Via Electronic Submission

Re: Medicare Programs; Revision to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule; CMS-1403-P

Dear Acting Administrator Weems:

The American Society of Plastic Surgeons (ASPS) is the largest association of plastic surgeons in the world, representing surgeons certified by the American Board of Plastic Surgery. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, and cancer. ASPS promotes the highest quality patient care, professional, and ethical standards and supports education, research and public service activities of plastic surgeons.

ASPS offers the following comments on the Center for Medicare and Medicaid Services (CMS) proposed rule for "*Medicare Programs; Revision to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule; CMS-1403-P*" that was published in the Monday, July 7, 2008 *Federal Register*. As requested in

the proposed rule, the relevant "issue identifier" that precedes the section we are commenting on is used as a sub-heading to assist the Agency in reviewing these comments.

Resource-Based PE RVU's

Equipment Time-in-Use

The Centers for Medicare & Medicaid Services (CMS) continues to assume equipment is in use 50 percent of the time a physician's office is open. ASPS reiterates its request that CMS officials consider alternative utilization rates based on recommendations from the RUC and others provided during this comment period.

Budget Neutrality Adjustment

The Medicare Improvements for Patients and Providers Act of 2008 requires that the budget neutrality adjustment be applied to the conversion factor, instead of work relative values. As we have expressed in previous comments to CMS, applying a budget neutrality adjustment to the work relative values is inappropriate; it is our position that the current change will protect the relativity of services in the RBRVS. However, we recommend that CMS publish a table showing the changes in calculations for all the codes or those codes that will be greatly affected by the change.

ERSD Provisions

Application of the Hospital-Acquired Conditions Payment Policy for IPPS Hospitals to Other Settings

In the proposed rule, CMS discusses the potential for the HAC payment provision to be applied to Medicare payment systems for other settings of care including the outpatient prospective payment system (OPPS), ambulatory surgical centers (ASCs), skilled nursing facilities, home health care, end-stage renal disease facilities, and physician practices. However, under the Deficit Reduction Act of 2005, Congress specifically provided CMS with the authority to begin applying the HAC policy to the hospital inpatient setting. In order for CMS to extend this policy to other settings, it would need similar statutory authority granted by Congress. Thus, under the existing statutory framework, it is our view that CMS cannot extend the inpatient HAC policy to the OPPS nor to other settings, such as ASCs or physician office practices.

ASPS has articulated numerous concerns about the HAC list, most recently in our comment letter on the inpatient prospective payment system (IPPS) rule. We strongly oppose expanding the HAC payment provision to ambulatory settings. The efficacy of the HAC provisions has yet to be validated in the inpatient setting. Specifically, it has yet to be proven that the HACs are reasonably preventable through the application of evidence-based guidelines, developed by appropriate medical specialty organizations based on non-biased, well-designed, prospective, randomized studies. Moreover, there has yet to be an analysis of: 1) the impact of the current HAC inpatient policy on quality of care relative to the additional Medicare costs required to comply with the HAC requirements; 2) the need for better risk adjustment techniques; 3)

attribution issues with respect to when, where and why a condition has occurred; and, 4) the reasonable number of expected incidence of these conditions in individual hospitals especially with regard to high-risk patients—when evidence-based guidelines are followed. We, therefore, urge CMS to conduct an analysis of the current HAC policy, in consultation with technical experts, physician organizations, hospitals and other impacted providers. Such analysis must occur before considering extension of this approach to other settings.

If these measures are implemented in the ambulatory setting, the likely result is that plastic surgeons will stop participating in the Medicare program. This is not a desirable outcome for ASPS members, for patients, and, presumably, for the Medicare program. Before pursuing plans to expand this concept, ASPS urges CMS to carefully consider all comments and make significant changes before attempting to apply the provision to other settings.

Physician Self-Referral and Anti-Markup Issues

Anti-Markup

The proposed rule discusses two alternative approaches to revising the anti-markup provision. The first alternative proposes to maintain much of the current regulatory language with clarification of several points. Specifically, CMS proposes to clarify that the "office of the billing physician or other supplier" includes space in which diagnostic testing is performed; in the same building that the billing physician or other supplier regularly provides their full range of patient care services. However, this does not include a mobile vehicle, van, or trailer in the parking lot of such building.

Under CMS' second alternative, it is proposed that the anti-markup policy will apply in all cases where the professional component (PC) or technical component (TC) of a test is either: (a) purchased from an outside supplier or (b) performed or supervised by a physician who does not share a practice with the billing physician or physician organization. CMS notes that a physician who is an employee of or independent contractor with, more than one billing physician or physician organization would not be viewed as sharing a practice. The ASPS supports CMS' proposal to exempt from the anti-markup policy those cases in which the PC or TC of a test is performed or supervised by a physician who shares a practice with the billing physician or physician organization. CMS insists that only an employee of or independent contractor with a single billing physician organization is viewed as sharing a practice with the billing physician. However, we believe that 2 or 3 such relationships should still be viewed as sharing a practice. This less restrictive approach would account for different practice situations while still providing considerable protection against Medicare program abuse.

The ASPS appreciates that CMS has recognized the limitations the current Anti-Markup language would have on legitimate practice arrangements. However, we remain concerned that the regulatory language does not address all legitimate practice arrangements. In our opinion, it would be advisable to delay implementation of this provision until January 1, 2010. As a result of the revisions made, it will be difficult for physicians to fully understand the rule and, if necessary, make changes in their practices to comply with the provision. We expect that this will

create unintended consequences (i.e. Medicare patients will be inconvenienced if their provider stops providing diagnostic tests).

Physician Self-Referral

ASPS supports the CMS proposal to create a Medicare physician self referral exception relating to hospital incentive payment and shared savings programs. However, we are concerned that some of the safeguards to be included in the exception are too limited.

ASPS is troubled that CMS is proposing to limit participation to "pools" of five or more participants. This safeguard would exclude participants in rural hospitals or other hospitals that do not have five or more physicians in a particular specialty.

Another concern is the proposed requirement, that a physician must be a member of the hospital staff at the commencement of the program. We believe that an exception needs to be made for physicians who are new to practice or new to the community.

CMS is proposing that remuneration paid to participating physicians or a qualified physician organization cannot include a greater volume of Federal health care patient procedures or services than the volume provided by the participating physicians or qualified physician organization during the period of the same length immediately preceding the commencement of the program. We propose that consideration be given for increased volume of Federal health care patient procedures and services due to market forces and physician practice growth, by a reasonable percentage over the baseline volume.

Physician Quality Reporting Initiative (PQRI)

In the proposed rule, CMS discusses, in detail, plans for extending the Physician Quality Reporting Initiative (PQRI) through 2009. Although the proposed rule does not authorize an incentive payment for PQRI 2009, the Medicare Improvements for Patients and Providers Act of 2008 provides a 2.0 percent incentive payment and extends PQRI reporting into calendar year 2010. The ASPS strongly supports the quality improvement goals of PQRI, however, we have serious concerns with certain aspects of the program.

PQRI Transparency/ Chronic Wound Care Measures

The ASPS strongly encourages CMS to ensure greater transparency in all aspects of developing the PQRI program, and especially with respect to the process of measure selection. Specifically, ASPS is perplexed, because it is unclear why certain measures are not included in the list of proposed measures for the 2009 PQRI. ASPS is particularly concerned that five of the seven Chronic Wound Care measures, {listed below}, submitted by PCPI are not included in the proposed rule and thus will not be part of the 2009 PQRI. We believe that the inclusion of all seven Chronic Wound Care measures is important, because they provide certain physicians for whom no other PQRI measures are applicable to their practice an opportunity to participate.

Furthermore, ASPS is confident that the seven performance measures we are recommending, which include two overuse measures and two patient education measures, are based on the best evidence available and have been designed for use by physicians and other health care providers. The multi-disciplinary stakeholders on the Work Group agreed that each of the measures addressed a significant gap in care.

Inclusion of all seven Chronic Wound Care measures will provide an excellent opportunity to begin closing a gap in care, which CMS has identified, and increase opportunities for participation in the PQRI. Additionally, in an effort to increase transparency, we urge CMS to provide in the final rule a thorough explanation of why these measures were not included in the list of measures proposed for the 2009 PQRI.

The Chronic Wound Care measures that were submitted to CMS by the PCPI but were not included in the proposed list of measures for 2009 are as follows:

Wound Care	Chronic Wound Care: Assessment of wound characteristics in patients undergoing debridement
Wound Care	Chronic Wound Care: Patient education regarding diabetic foot care
Wound Care	Chronic Wound Care: Patient education regarding long term compression therapy
Wound Care	Chronic Wound Care: Use of superficial swab culture in patients with skin ulcers (overuse measure)
Wound Care	Chronic Wound Care: Use of wet to dry dressings in patients with skin ulcers (overuse measure)

PQRI 2009

ASPS is pleased that CMS will continue the use of alternative reporting options; originally implemented in April 2008. We believe that the additional reporting options provide more flexibility and opportunities for physicians to participate in the PQRI. However, we strongly suggest that CMS initiate a strong educational program aimed at helping participating physicians successfully report data under the 2009 PQRI.

The ASPS remains committed to measuring and improving the quality of patient care, and continues to be actively engaged in performance measurement and quality improvement efforts.

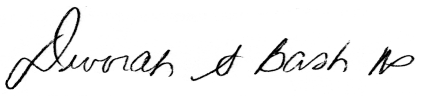
Potentially Misvalued Services Under the PFS

The proposed rule recognizes both continuing concerns regarding misvalued services under the Medicare physician fee schedule and ongoing work by the RUC to address these concerns by creating a Five-Year Review Identification Workgroup.

The ASPS appreciates that CMS has asked the RUC to undertake this review of potentially misvalued codes and we look forward to working with the RUC and CMS on such review.

As always, we appreciate your consideration of these comments. We will continue to carefully monitor future correspondence on these and other relevant health care issues.

Sincerely,



Deborah Bash, MD
Chair, Payment Policy Committee